

## SPECIALTY GUIDELINE MANAGEMENT

### FORTEO (teriparatide) BONSITY (teriparatide) TERIPARATIDE

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indications

- A. Treatment of postmenopausal women with osteoporosis at high risk for fracture
- B. Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture
- C. Treatment of men and women with glucocorticoid-induced osteoporosis at high risk for fracture

All other indications are considered experimental/investigational and not medically necessary.

##### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Supporting chart notes or medical record indicating a history of fractures, T-score, and FRAX fracture probability as applicable to Section III.

##### III. CRITERIA FOR INITIAL APPROVAL

##### A. Postmenopausal osteoporosis

Authorization of an initial total of 12 months for parathyroid hormone analogs (e.g., abaloparatide or teriparatide) may be granted to postmenopausal members with osteoporosis when ANY of the following criteria are met:

1. Member has a history of fragility fractures
2. Member has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (See Appendix B) and meets ANY of the following criteria:
  - a. Member has indicators of higher fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores [less than or equal to -3.5], or increased fall risk)
  - b. Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], denosumab [Prolia])
  - c. Member has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate (See Appendix A)

##### B. Primary or hypogonadal osteoporosis in men

Authorization of an initial total of 12 months for parathyroid hormone analogs (e.g., abaloparatide or teriparatide) may be granted to male members with primary or hypogonadal osteoporosis when ANY of the following criteria are met:

1. Member has a history of an osteoporotic vertebral or hip fracture
2. Member meets criteria BOTH of the following criteria:
  - a. Member has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (See Appendix B)
  - b. Member has had an oral OR injectable bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with a bisphosphonate (See Appendix A)

### C. Glucocorticoid-induced Osteoporosis

Authorization of an initial total of 12 months for parathyroid hormone analogs (e.g., abaloparatide or teriparatide) may be granted for members with glucocorticoid-induced osteoporosis when ALL of the following criteria are met:

1. Member has had an oral OR injectable bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with a bisphosphonate (See Appendix A)
2. Member is currently receiving or will be initiating glucocorticoid therapy
3. Member meets ANY of the following criteria:
  - a. Member has a history of a fragility fracture
  - b. Member has a pre-treatment T-score less than or equal to -2.5
  - c. Member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (See Appendix B)

## IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving the requested medication through a paid pharmacy or medical benefit, AND have received less than 24 months of total lifetime therapy with parathyroid hormone analogs (e.g., abaloparatide or teriparatide).

## V. APPENDIX

### Appendix A. Clinical reasons to avoid oral bisphosphonate therapy

- Esophageal abnormality that delays emptying such as stricture or achalasia
- Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)
- Inability to stand or sit upright for at least 30 to 60 minutes
- Inability to take at least 30 to 60 minutes before first food, drink, or medication of the day
- Renal insufficiency (creatinine clearance < 35 mL/min)
- History of intolerance to an oral bisphosphonate

### Appendix B. WHO Fracture Risk Assessment Tool

- High FRAX fracture probability: 10 year major osteoporotic fracture risk  $\geq$  20% or hip fracture risk  $\geq$  3%.
- 10-year probability; calculation tool available at: <https://www.sheffield.ac.uk/FRAX/>
- The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day.

## VI. REFERENCES

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